

REMARKS

Reconsideration of this application is respectfully requested.

Claim 1 has been amended. Two additional features are added to the claims, (1) the non-solvent is miscible to the solvent for the polymer, and (2) the non-solvent and the curing agent are limited to 10 specific pairs of solvents. Support for the amendment to claim 1 can be found at original claim 2, and Example 1, a), b), and c).

WO '799 teaches a process for encapsulating active agents to form controlled-release microparticles through the use of static mixers. The process can be carried out for a variety techniques used to encapsulate active agents, such as a solvent extraction technique or a phase separation technique (page 8, lines 14-16 or page 29, lines 4-9).

According to the solvent extraction technique, a first phase containing the polymer and the active agent and a second aqueous phase comprising a surfactant are combined to form an emulsion. In that case, the first phase and the second phase must be immiscible (page 8, lines 10-11; page 10, lines 23-24; page 11, lines 2-3).

Microdroplets form during the emulsion phase. Microparticles are recovered from the quench liquid.

The presently claimed process does not use a solvent extraction technique since the solvent of the polymer is miscible with the non-solvent. The presently claimed process rather uses a phase separation technique. A conventional example of this technique is described at pages, line 9 - page 6, line 2 of WO '799. The process of WO '799, which uses the phase separation technique, is described at page 29, lines 4-17. Examples of using such process are provided at Examples 11-14.

With the phase separation technique, WO '799 teaches the use of silicon oil as a non-solvent, ethyl acetate as the solvent of the polymer and heptane as the quench liquid (or curing agent). (See page 29, lines 11-15 and Example 11-14)

The pairs of non-solvent/curing agent, which are recited in claim 1, are not taught or suggested by WO '799. Furthermore, these solvents are chemically very different to silicon oil or heptane. Silicon oils are a chain of polydimethylsiloxane (PDMS). By contrast, in the presently claimed invention, the non-solvent is selected from alcohols or a ketone containing 2 to 3 carbon atoms. Heptane is an alkane containing seven carbon atoms. By contrast, in the presently claimed invention, the curing agent is selected from water or an alcohol containing 1 to 4 carbon atoms. In WO '799, there is no motivation to replace silicon oil with 1,2-propanediol, glycerol, 2-propanol, ethanol or methylethylketone, and to replace heptane with 2-propanol, 1,2- propanediol or water.

Furthermore, WO '799 teaches the use of a static mixer. sWO '799 emphasizes the difference between dynamic mixing and static mixing (page 20, line 23 - page 23, line 14 + figure 1 and 2; page 20, line 19 - page 21, lines 19 and 22). In WO '799, it is said that the conventional techniques for the microencapsulation of active agents that involve stirring, agitating, vibrating, or other dynamic mixing techniques, have several drawbacks (see page 6, lines 11 -16):

- it is difficult to control the size of the resulting microparticles, or the distribution of sizes obtained,
- the production equipment to stir or agitate fluids is expensive,
- the overall production process time is long,
- because of the long time process, the active agent may deteriorate,

- scale-up to a production process from a laboratory emulsion is difficult and must be empirically optimized, and
- particle size control becomes less reliable as batch size is increased (see page 6, line 17 to page 7, line 20).

WO '799 teaches a process which overcomes all these drawbacks, by using a static mixer.

The presently claimed process allows microencapsulation of active agents with non-chlorinated solvents as well, but using dynamic stirring and providing that the solvent, non solvent, and curing agents are selected from those mentioned in claim 1. These particular conditions are not taught nor suggested by WO '799. Therefore, the presently claimed process is non-obvious in view of the process disclosed in WO '799

Applicants respectfully request entry of this Amendment.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: November 16, 2005

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